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EXAMINER	
PANI, JOHN	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/520,507	Applicant(s) CROSSMAN ET AL.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pgs. 9-10 ("The Drawings"), filed 2/1/2010, with respect to the drawings have been fully considered and are persuasive. The objection of 8/31/2009 has been withdrawn.
2. Applicant's arguments, see pg 11 ("Rejection Under 35 USC §112, Second Paragraph"), filed 2/1/10, with respect to claims 1-5, 8-10 and 15-19 have been fully considered and are persuasive. The rejection of 8/31/09 has been withdrawn.
3. Applicant's remaining arguments filed 2/1/10 have been fully considered but they are not persuasive. In response to Applicant's assertion that "the cap 12 of Koike et al is not releasably attached to the lancet adjacent its needle; instead, the cap is non-releasably attached to the cover which itself is releasably attached to the lancet adjacent its needle", the Examiner respectfully disagrees. First, the Examiner submits that a structure can be attached to another structure via an intermediate structure (the cover 22" in this case). Second the Examiner submits that it is apparent that cover 22" was interpreted in the previous Action as part of the claimed cap, as the claim requires "cap extending to project...and having at least one locating member", and 22" was cited to be a part of the locating member, thus showing that 22" was interpreted to be part of the claimed "cap". This interpretation further obviates Applicant's assertion that "cap does not project at all through an opening in the housing but instead the cap is attached to the cover and the cover extends through the housing".

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4. In response to Applicant's assertions that the cap of Koike "does not have a locating member which fits into a cooperating feature of outer walls of the housing; the cap does not have any such features but merely fits over the end of the housing, having what appears to be a cylindrical bore which slides over the cylindrical outer surface of the housing", the Examiner respectfully disagrees. First, it is noted that as clearly recited in the previous Action, the locating member has been interpreted to include "22" and grooves in 12" located to each side of 22"". Further, the Examiner notes that the claim does not clearly define the term "outer walls of the housing". For example, portion 15 could be interpreted as an "outer wall of the housing" relative to the portion located inside structure 3 shown in Fig. 18C. In this interpretation, the locating member as defined above clearly "fit[s] into at least one cooperating feature of outer walls of the housing" (in this case the cooperating feature being the distal opening of 1). In an additional/alternative interpretation, it is noted that one definition of the term "into" is "against" ("into." The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 29 Apr. 2010. <[Dictionary.com http://dictionary.reference.com/browse/into](http://dictionary.reference.com/browse/into)>.), and that even giving the term "outer walls" a stricter interpretation as the exterior of the housing, the grooved portion of 12" surrounding 15 clearly fits "against" the exterior of 15. Because the "locating feature" has been interpreted to be various parts of cap 12 and 22", removing the locating member from the cooperating feature detaches the cap from the housing and the lancet. Therefore, it is respectfully submitted that Koike does in fact disclose the disputed limitation.

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5. In response to Applicant's assertions that "Claim 2 is distinguished because the features discussed in Claim 2 relate to a feature on the cap and a feature on the housing, the features the Official Action refers to are features on the cap 12" and the cover 22'", the Examiner respectfully disagrees and notes that the claimed "locating member" has been interpreted to include the groove in 12" surrounding cooperating feature 15, and 15 is clearly a flange on the greater housing 1. In other words, the locating member *is* a groove, and the cooperating feature *is* a flange.

6. In response to Applicant's assertions regarding claim 11 that "Koike does not disclose a cap having a first end releasably attached to the lancet body and a second end that is releasably attached to the housing by a locating member that fits into a cooperating feature on the outer wall of the housing", the Examiner respectfully disagrees and notes that 22" has been interpreted to be part of the cap, and this end of the cap is clearly releasably attached to the lancet body. The end opposite this attachment is a second end and is clearly "releasably attached to the housing" as claimed.

7. In response to Applicant's assertions that Marshall does not disclose a cap "adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of the trigger releasable latch until said cap is detached from the lancet", the Examiner respectfully disagrees. The limitation has been interpreted as an intended use limitation which merely requires sufficient structure to perform the claimed holding. Examiner submits that by virtue of the length of section 20 it could be used by a person to hold the lancet as claimed.

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8. In response to applicant's argument that Haynes does not teach "an arrangement for a device in which the cap fulfills any other function than closing the neck and certainly not an arrangement where the cap extends through the neck of the housing to interact with a mechanism inside the housing to prevent its operation", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Particularly, the Examiner notes that Koike explicitly discloses that the cap prevents the lancing needle from being exposed to the air (see [0072]). Haynes teaches including the cited structures in order to indicate whether the container has been opened. It is submitted that one of ordinary skill in the art would recognize the applicability of this structure to the device of Koike, as they would recognize the benefits of allowing a user to determine whether the lancet had been exposed to air or not. The modification of the pre-cocked embodiment of Marshall by Koike discloses the cap extending through the neck of the housing.

9. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "the cap holds the latch surfaces spaced apart, against the influence of the drive spring, until the device is ready to be used") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1, 2, 11, and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/005907 to Koike et al. (“Koike”).

Please note that US 2004/0243165 has been used herein as an English language translation for WO 03/005907, as US 2004/0243165 is a publication of the National Stage entry of PCT/JP02/07030. References to paragraph numbers below are made with respect to the US publication. It is noted that the drawing and reference numbers are identical for the two publications.

Koike teaches:

In reference to Claim 1

A blood sampling device comprising: a needle-carrying lancet (2) located within a housing (1) and having a cap (12”) releasably attached to said lancet adjacent said needle (20), the cap extending to project from an attachment to said lancet through an opening at one end of the housing (see Fig. 16) and having at least one locating member (22” and grooves in 12” located to each side of 22”) fitting into at least one cooperating feature (distal wall and distal opening of 1) of outer walls of the housing, and the cap holds the lancet against movement relative to the housing (see Fig. 16), the

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cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet (see [0088]).

In reference to Claim 2

The blood sampling device of claim 1 (see above) wherein the at least one locating member and the at least one cooperating feature are fitted together via a groove cooperating with a flange or a rib (see Fig. 16, the "locating member" is the groove in 12 between 12 and 22" and the cooperating feature is flange 15).

In reference to Claim 11

A blood sampling device comprising: a housing (1) having an opening (space 22" resides in), a lancet body (2) carrying a needle (20), the lancet body being movably mounted within the housing and arranged so the needle momentarily projects through the opening of the housing upon actuating the blood sampling device (see Figs. 12A-12C), a cap (12") having a first end (23) releasably attached to the lancet body and covering a tip of the needle (Fig. 16), the cap extending through the opening of the housing to a second end that is releasably attached to the housing by at least one locating member (e.g. 22" and the groove in 12" surrounding 22") on the second end that fits into at least one cooperating feature (distal walls of 1 and distal opening in 1) on an outer wall of the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature so the cap can be removed from the housing and the lancet body (see [0088]), the cap, the housing and the lancet body

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being arranged to prevent forward movement of the needle relative to the housing prior to removal of cap and actuation of the blood sampling device (see Fig. 16).

In reference to Claim 12

The blood sampling device of claim 1 (see above) wherein the cap is twistable to remove the cap's attachment to the housing and the cap's attachment to the lancet (see [0088]).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 4, 5, 8, 10, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,487,748 to Marshall et al. ("Marshall") in view of Koike.

In reference to Claims 4, 5, 8, 10, and 15

Marshall teaches a blood sampling device comprising: a housing (1, 2); a spring loaded (2) needle-carrying lancet (8) located within the housing; a cap (20) releasably attached to said lancet adjacent said needle (17); and a trigger releasable latch (23, 12, etc.) to hold the lancet within the housing such that an exposed needle cannot project through an opening at one end of the housing until the latch is released by the trigger (9) (see at least col. 3), the cap extending to project from an attachment to said lancet through the opening (4) at one end of the housing (Fig. 1), the cap being twistable to

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release the at least one locating member from the lancet (col. 3 lines 10-15), the lancet being spring-loaded to urge the lancet in a direction towards the opening in the housing, wherein said trigger releasable latch and said lancet have respective opposed latch surfaces (12, 23) cooperable to retain said lancet in said housing until release of said latch, and said cap is adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of said trigger-releasable latch until said cap is detached from the lancet (see Fig. 1). Marshall further teaches that the device can be made in a pre-cocked version (col. 2 lines 40-50).

However, Marshall does not explicitly teach that the cap has at least one locating member fitting into at least one cooperating feature of outer walls of the housing, and the cap holds the lancet against movement relative to the housing, the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet. Koike teaches a lancet device (see at least Fig. 16) in which the cap (12") has at least one locating member (22" and grooves in 12" surrounding 22") fitting into at least one cooperating feature (distal end of 1 in addition to distal hole in 1) of outer walls of the housing, whereby the cap holds the lancet against movement relative to the housing (see Fig. 16), the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet (see [0088]). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Marshall by modifying the cap of the pre-cocked version so that it was attached to the

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outer walls of the housing as taught by Koike in order to provide a more secure shipping configuration as implicitly taught by Koike.

In reference to Claim 16

Marshall in view of Koike teaches the device of claim 15 (see above) and Koike teaches the at least one locating member and the at least one cooperating feature are fitted together via a groove cooperating with a flange or a rib (see Fig. 16, the "locating member" is the groove in 12 between 12 and 22" and the cooperating feature is flange 15).

14. Claims 3, 9, 13, 14, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike or Marshall in view of Koike (as applicable) as applied to claims 1, 2, or 17 (as applicable) above, and further in view of US Pat. No. 3,165,220 to Haynes ("Haynes").

In reference to Claims 3, 13, 17, 18, and 20-22

Koike teaches the device of claims 1, 2 and 11 (see above). Marshall in view of Koike teaches the device of claim 15 (see above). However, neither Marshall nor Koike explicitly teach two flanges fitting into grooves in two opposed sides of outer walls of the housing or that the head of the cap can be rotated 90 degrees to release flanges from notches in two sides of the housing (see Fig. 5, a 90 degree rotation would release the flanges from the notches). Haynes teaches a tamper-proof container enclosure in which the cap includes two flanges (**34**) while the container includes grooves (**18**). The device includes frangible buttons/pins **28** which when broken, indicate that the original

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seal has been broken (see col. 1 line 60 – col. 2 line 60). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Koike or Marshall in view of Koike by including a tamper-proof enclosure using flanges, grooves, and pins as taught by Haynes, in the sealed cap taught by Koike, so the user could know whether the device was previously opened as taught by Haynes.

Regarding claims 20-22, this combination would be such that the cap would hold the lancet against at least a forward movement relative to the housing (note that the closure method of Haynes includes a hook 34 under a flange 16 which would prevent forward movement; additionally, while it is not explicitly discussed with regards to the embodiment of Figs. 16-18C of Koike, it appears that the cap is somehow sealed to the body, as like all of the other embodiments, it requires twisting and pulling to remove the cap prior to use [0102]; in other words, the force produced by driving means Y which forces 121 into 120 is not sufficient to force 120 off the casing, so it appears the cap prevents forward movement past the configuration shown in Fig. 18B until the cap is twisted off).

In reference to Claim 9

Marshall in view of Koike and Haynes teaches the device of claim 3 (see above), and Marshall further teaches the lancet is spring-loaded to urge the lancet in the direction towards the opening in the housing (via 7, see Fig. 1).

In reference to Claims 14 and 19

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Marshall in view of Koike and Haynes teaches the device of claims 13 and 18 (see above) and Marshall further teaches the lancet can move forward until a ledge (23) on the lancet locates against a flange (12) on a trigger member.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 4/29/10

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736